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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,447	05/08/2006	Henning Braess	PHOE030380US	6977

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595 MINER ROAD
CLEVELAND, OH 44143

EXAMINER

BITAR, NANCY

ART UNIT	PAPER NUMBER
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2624

MAIL DATE	DELIVERY MODE
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10/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,447	Applicant(s) BRAESS, HENNING	
	Examiner NANCY BITAR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2008 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/25/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/25/2008 have been fully considered but they are not persuasive.
2. Applicant amended claims 1-8, 10. Claims 11-17 have been added. Claims 1-17 are currently pending.
3. Applicant argues that all three references disclose an image producing device and none of three applied reference disclose a TOF-PET unit for recording a concentration of PET scanner. Examiner refer to Ogino et al (US 6,985,613) teaches in capturing the blood flow image, a time-of-flight (TOF) technique, phase contrast (PC) technique or the like is employed (see figure 3, column 11, lines 48-63) . Moreover, Ogino imaging apparatus is not limited to MRI apparatus but may be any other type of imaging apparatus, such as an X-ray CT (computed tomography) apparatus, an X-ray imaging apparatus, PET (positron emission tomography) or a .gamma.-camera. Applicant argues that all the three reference disclose a data processing, but none of the data processing unit which determines a spatial position of a body volume that is filled with blood and positions the TOF-Pet unit such that the volume element of the TOF-PET unit lies in the blood filled body volume (note that this limitation is newly added in claim 1 and will be addressed in the rejection below)Moreover, Applicant argues that no one modify the data processing unit .Ogino teaches the spatial position in (figure 12-13) and The effect of the gradient magnetic fields and high frequency magnetic field on the spins is different between the spins that move inside the body such as those in blood flow, and the spins that do not move such as those in a tissue. By using this difference, an image of the spins that move inside the body,

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i.e., for example, a blood flow image may be captured. Moreover, Ogino teaches blood flow imaging is performed at Step 302. For the blood flow imaging, a time-of-flight (TOF) technique, phase contrast (PC) technique or the like is employed. Moreover, the imaging is performed in multi-slice. Thus, multi-slice blood flow tomographic images $S_1, S_2, S_3, \dots, S_m$ are captured with respect to a three-dimensional region of the object 300, as conceptually shown in FIG. 4. Next, at Step 304, pixel value adjustment is performed on the blood flow tomographic images $S_1, S_2, S_3, \dots, S_m$. The pixel value adjustment is implemented by the data processing function of the data processing section 170. The blood flow tomographic image will be referred to simply as an image (see figure 15, the blood flow images b_1, b_2). All remaining arguments are reliant on the aforementioned and addressed arguments and thus are considered to be wholly addressed herein.

Election/Restrictions

4. Newly submitted claim 12-16 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 12-16 teaches detecting pairs of annihilation quanta from a PET tracer in blood with the pair of TOF-PET detectors and using the time of flight information to identify pairs of annihilation quanta emitted from the blood filled body volume and generating temporally dynamic PET images of another region of the patient concurrently with determining the concentration of Pet tracer in blood in addition to the limitations of claims 13-16. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

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merits. Accordingly, claims 12-16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

5. The information disclosure statement filed 06/25/2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because no English translation has been provided.. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the dynamic PET data" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Examiner Notes

8. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations

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are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino et al (US 6,985,613) in view of Salem et al (X-ray computed tomography methods for in vivo evaluation of local drugs release systems, IEEE 2002) and Lambrecht et al (US5,019,323)

Ogino et al teaches a device for the in vivo determination of the concentration of a PET tracer in blood, including: an image-producing device which generates a the locally resolved depiction of a region of the body (100, figure 1) including a body volume which is filled with blood and a data processing unit (data collection section, 150, figure 1) which is coupled to the image-producing device and the TOF-PET unit(the blood flow image, a time-of-flight (TOF) technique, phase contrast (PC) technique or the like is employed (column 11, lines 48-67), the data processing unit in conjunction with the

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image producing device determines a spatial position of the body volume that is filled with blood (figure 14-15), and determines detector element position of the (TOF-PET unit such that the volume element of the TOF-PET unit lies in the body volume that is filled with blood (blood flow imaging, a time-of-flight (TOF) technique, phase contrast (PC) technique or the like is employed, column 11, lines 50-63, note that Thus, multi-slice blood flow tomographic images $S_1, S_2, S_3, \dots, S_m$ are captured with respect to a three-dimensional region of the object 300, as conceptually shown in FIG. 4). While Ogino meets a number of the limitations of the claimed invention, as pointed out more fully above, Ogino fails to specifically teach the in vivo determination of the concentration of a PET tracer. Specifically, Salem et al. teaches the use of X-ray Ct imaging is a useful technique for the in vivo evaluation of the pharmacokinetics of platinated agents (page 1310, paragraph 1) .Moreover, Salem et al teaches We utilized a 3-D registration method to spatially align the sequence of temporal CT volumes in order to spatially examine drug distributions at different times in order to permit the determination of optimal carboplatin concentration-time relationship. it would have been obvious to one of ordinary skill in the art to use ton the in vivo determination of the concentration in Ogino imaging system in order (to permit rational design of drug delivery systems with optimal drug dosage ,release rate, and duration to provide a safe and effective localized drug therapy (page 1316, paragraph 2). Lambrecht teaches the positrons, which have maximum end point energy of 2.1 MeV, interact with matter and annihilate into two photons of about 511 keV energy at about 180 degree referenced to the point of annihilation. The annihilation quanta are readily detected by PET instruments. Moreover, Lambrecht teaches Positron camera imaging can be used to evaluate the therapy.

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Other gamma radiation associated with the radioactive decay of Iodine-124 does not cause appreciable interference with imaging the positron annihilation photons. It would have been to one of the ordinary skill in the art to use the Pet tracer of Lambrecht in combination of an image producing device of Ogino with a time of flight PET in order to reduce the time of the calibration and enables simple, possibly also dynamic or subsequent fixing of the volume element under examination thus the concentration of the tracer in the blood is measured precisely. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 2, Lambrecht et al. teaches the device as claimed in claim 1, wherein the TOF-PET unit comprises: two gamma detector elements that detect pairs of annihilation quanta the two gamma elements lie opposite one another and define the predetermined volume element on a line therebetween, and corresponding evaluation electronics unit for recording times of flight of the pairs of detected annihilation quanta (The positrons, which have a maximum end point energy of 2.1 MeV, interact with matter and annihilate into two photons of about 511 keV energy at about 180 degree referenced to the point of annihilation. The annihilation quanta are readily detected by PET instruments (column 7, lines 3-68).

As to claim 3, Lambrecht et al. teaches the device as claimed in claim 2, wherein the effective area of each detector element is between approximately 10 mm.² and 400 mm.² (figure 1)

As to claim 4, Ogino teaches the device as claimed in claim 1, wherein the image-produce and x-raying device includes one of an MRI device and an X-ray projection device (x-ray CT (computed tomography) apparatus, an X-ray imaging apparatus, PET(positron emission tomography) or a .gamma.-camera, column 17, lines 4-9).

As to claim 5, Ogino teaches the device as claimed in claim 1, a PET device for preferably three-dimensional recording of the distribution of the PET tracer in a body region (A blood flow projection image in a three-dimensional region is obtained by using one of these techniques to capture multi-slice blood flow tomographic images with respect to the three-dimensional region, and performing maximum intensity projection (MIP) on the multi-slice blood flow topographic images in the slice thickness direction(column 1, lines 32-38, see also Salem et al, page 1312, column 2, paragraph B).

As to claim 6, Ogino teaches the device as claimed in claim 1, wherein the data processing unit is set up to segments into images produced by the image-producing device to identify the body volume that is filled with blood (see figure 16, see also Lambrecht teaches annihilation quanta are readily detected by PET instruments) .

As to claim 7, Ogino teaches the device as claimed in claim 1, further including a display device for displaying images that have been produced with the image-producing device, and an input means for interactive selection of a body volume in the displayed images (The data processing section 170 is connected with a display section 180 and an operating section 190. The display section 180 comprises a graphic display, etc. The operating section 190 comprises a keyboard, etc., provided with a pointing device, Column 10, lines 56-67)

As to claim 8, Ogino teaches the device as claimed in claim 1, wherein the body volume filled with blood lies in an aorta or in the left ventricle of the heart (the blood flow images b1' and b2', figure 15).

The limitation of claims 9-11 has been addressed above
The limitation of claim 17 has been addressed above except for the following controlling the position of the two detectors .Ogino teaches the control section in figure 1,160.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Bitar

10/20/2008

/Jingge Wu/

Supervisory Patent Examiner, Art Unit 2624